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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,530	11/13/2003	Andrew Thomas Forsberg	47563.0014	9304

7590 01/29/2007
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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/713,530

Applicant(s)

FORSBERG ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 2-12, 22-27 and 31-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13-21, 28-30 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 13-16, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,179,863 to Kensey et al.

Kensey discloses several embodiments of blood vessel wall locators. The embodiment in Figure 27 includes a dilator (300), insertion sheath (28) with a first inlet port (304) at its distal end, and an indicator (28E) coupled to the port (304) (column 10, lines 24-53). The first lumen in this embodiment is between the dilator and sheath. The embodiment in Figure 29 includes a dilator (400) with an inlet port (404) at its distal end, insertion sheath (28), and an indicator (28E) coupled to the port (404) (column 10, line 54 – column 11, line 6). The lumen in this embodiment is within the dilator. The embodiment in Figure 31 includes a dilator (600), insertion sheath (28) with an inlet port (506) at its distal end, and an indicator (28E) coupled to the port (506) (column 11, lines 8-24). The lumen in this case is within the wall of the sheath. Kensey describes the indicator as a stopcock (28E) that allows blood to flow out of its lumen (column 11, lines 25-40). This is considered to meet the limitation “drip hole.”

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 17-21, 28-30, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al.

Kensey fails to disclose an embodiment including a first inlet port in the dilator and a second inlet port in the insertion sheath. Kensey does disclose both locations of inlet ports but in separate embodiments. The introducer sheaths of Figures 27 and 31 with inlet ports are capable of receiving the dilator of Figure 29 with an inlet port. Kensey suggests the combination of these elements in lines 25-48 of column 11. One of ordinary skill in the art would be capable of providing a second drip hole when combining the structures. This modification would involve only routine skill in the art would increase the versatility of the components by allowing the user multiple modes of identifying blood vessel location.

Response to Arguments

3. Applicant's arguments filed 11/15/06 have been fully considered but they are not persuasive. Applicant's arguments are simply directed toward the intended use of the device. The new limitation "*first indicator provides indication of excessive penetration of the insertion sheath to the vessel*" is a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant's arguments failed to particularly point out structural deficiencies of the Kensey device. Kensey is not required to explicitly state the use of the device for indicating over-insertion. The Kensey device meets all the structural limitations and is capable of being used to indicate over-insertion of the device.

4. Applicant also argues that there is no motivation to combine the embodiments of Kensey. Though Kensey does not explicitly state that the obturator in Figure 29 can

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be inserted through the sheath of either Figure 27 or Figure 31, this combination would have been obvious to one of ordinary skill in the art. The combination does not require any modification to the structure of the components. One of ordinary skill in the art would have recognized advantages of this combination. With the obturator and introducer sheath both being capable of indicating blood flow, the versatility and user friendliness of the device are increased since the operator has multiple options for the use of the device.

5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW
1/11/07

JULIAN W. WOO
PRIMARY EXAMINER